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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/708,006	11/08/2000	Akihiro Kishishita	197759US00CONT	1289

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EXAMINER
ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 05/31/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,006

Applicant(s)

KISHISHITA ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Application may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Current Status

1. This action is responsive to Applicant's amendment 4 March 2002 in Paper No 13.
2. Receipt and entry of Applicant's amendment is acknowledged.
3. Claims 1-15 are outstanding.
4. The rejection under 35 U.S.C. 102(b) set forth in paragraph 8 of the previous Office Action in Paper No 11 is withdrawn.
5. The Examiner notes that Applicant has declined the opportunity to make a showing demonstrating how the change in solubility of Neotame upon drying to a water content of less than 3% is surprising in light of Wakamatsu's teaching as was discussed in the interview summarized in paper No 12.
5. Claims 1-15 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al (US 4,810,818 03-1989) and further in view of Nofre et al (US 5,480,668 01-1996).

The instantly claimed invention is a crystalline form of the Aspartame derivative Neotame, a process for its production and compositions comprising it.

Wakamatsu teaches (Column 3, lines 11-43) a method of producing a more easily soluble crystalline form or aspartame which comprises granulation and drying the aspartame to a water content of 2.6% by weight which meets the limitation of less than 3% of instant Claim 2. Wakamatsu further teaches (Column 2, lines 17-18) a

range of granule size of 0.1 to 10 mm which embraces the instant range of 100-1,400 μm (which corresponds to 0.1-1.4 mm).

Wakamatsu is silent with respect to the use of N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester (neotame) in this process as is instantly claimed.

Nofre, however, discloses (Column 4, line 65-Column 5, line 10) Neotame and its synthesis (Column 6, lines 27-54) from Aspartame to which it is a close analog.

Nofre further teaches (Column 1, lines 10-19) the use of Neotame as a sweetening agent in food and drinks as well as its use (Column 6, lines 16-26) in conjunction with other sweeteners such as sucrose and saccharin. Nofre further teaches (Column 6, lines 8-16) its use in conjunction with carriers or bulking agents such as polydextrose, starch, maltodextrins, and cellulose. Nofre teaches (Column 4, lines 29-37) the use of Neotame for all uses of the known sweetener aspartame.

Thus the instantly claimed invention would have been obvious to one of ordinary skill in the art. The motivation for performing this invention would have been to provide the same improved solubility for Neotame that the process of Wakamatsu provided for its close analog aspartame, a commercially important sweetener. Because of the very close structural similarity of Neotame and Aspartame and the large overlap in their intended uses the expectation for success would be very strong.

Response to Remarks

6. Applicant has made several remarks with regard to the Declaration in Paper No. 10:

- a. Applicant argues that the declaration does not disclose Neotame "crystals".

The Examiner agrees and did not indicate such in his response to the declaration. Applicant has demonstrated that Nofre discloses Neotame having 1.4% water content.

- b. Applicant refers to the "gummy precipitate" of Nofre as analogous to the product of paragraph 6 of the declaration. The Examiner fails to see the analogy since the starting material for the process described in this paragraph is presumably the solid "recrystallized" material corresponding to the final product of Nofre.
- c. Applicant further argues that Nofre does not disclose or suggest different crystalline forms having differing solubilities. This is correct. Wakamatsu teaches these elements.
- d. Applicant is correct that Wakamatsu teaches two different crystalline forms having differing solubilities. Wakamatsu further teaches (Column 2, lines 48-50) that once the water content reaches less than 5% the preferred, more soluble, crystalline form is stable and further drying may be accomplished at temperatures higher than 50°C.
- e. Applicant argues that Wakamatsu teaches a fundamentally different process. This is incorrect. Wakamatsu teaches a process for producing a crystalline form of Aspartame (of which Neotame is a derivative) having superior solubility properties by reducing its water content. Applicant's claimed process is fundamentally identical.

- f. Applicant's amendment of Claims 1 and 2 to recite a single X-ray powder diffraction angle renders these claims incapable of distinguishing the claimed crystal form over those of the prior art (See: In re Grose and Flanigen, 201 USPQ 57).

Applicant's arguments filed 4 March 2002 have been fully considered but they are not persuasive for the reasons set forth above.

New Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following new rejections were necessitated by Applicant's amendment and are therefore MADE FINAL.

Claim Rejections - 35 USC § 102

7. Claim 1 is finally rejected under 35 U.S.C. 102(b) as being anticipated by Nofre et al (US Patent 5,480,668 02-1996). Nofre discloses the synthesis of N-[N-(3,3-dimethylbutyl)-L-.alpha.-aspartyl]-L-phenylalanine 1-methyl ester (hereinafter "Neotame") and its crystallization (column 7, line 47-51). The powder diffraction characteristics of the Neotame crystal, although not disclosed by Nofre, are an inherent property of the prior art crystal. Because Applicant distinguishes the instant crystal from the prior art crystal on the basis of its diffraction characteristics such characteristics must be clearly and unambiguously set forth. The use of a single

diffraction angle is insufficient to distinguish Applicant's crystal over the prior art crystal (See: In re Grose and Flanigen, 201 USPQ 57).

Conclusion

8. Claims 1-15 are outstanding. Claims 1-15 are finally rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.


Art Unit: 1621

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker
Patent Examiner
Technology Center 1600

May 14, 2002


Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600